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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,471

02/27/2007

Tatsuya Konishi

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03/04/2009

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EXAMINER

KASSA, TIGABU

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,471	Applicant(s) KONISHI ET AL.	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/28/08 and 12/07/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Claims 8-14 are pending. Claims 1-7 are cancelled. Claims 8-14 are under consideration in the instant office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 provides for the use of benzocaine in the reduction of the skin irritation caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

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USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Note: For prior art purposes the examiner interpreted instant claim 14 as a method of reducing irritation of the skin caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient using benzocaine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Juni (US Patent No. 6120792).

Instant claim 8 recites an analgesic and anti-inflammatory patch comprising, as active ingredients, benzocaine and an ingredient having a counter-irritation effect. Instant claim 9 recites the analgesic and anti-inflammatory patch according to claim 8, containing benzocaine in an amount of 0.5 to 20 wt %. Instant claim 10 recites the analgesic and anti-inflammatory patch according to claim 9, wherein the ingredient having a counter-irritation effect is at least one selected from the list recited in the instant claim. Instant claim 14 recites use of benzocaine in the reduction of the skin irritation caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient.

Note: For prior art purposes the examiner interpreted instant claim 14 as a method of reducing irritation of the skin caused by an ingredient having a counter-irritation effect used in an analgesic and anti-inflammatory patch as an active ingredient using benzocaine.

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Juni discloses **a medicated skin patch for delivering a topical anesthetic to a region of skin which has been irritated**, the patch comprising a bibulous pad for contacting and covering the irritated region a thickened, topical anesthetic imbibed in the bibulous pad, said anesthetic comprising an active ingredient chosen from the group consisting of lidocaine, **benzocaine**, procaine, xylocaine, and combinations thereof (see claim 1). Juni discloses the medicated skin patch also contains an active ingredient of the counter-irritant composition chosen from the group consisting of **capsaicin, menthol**, and clove oil (see claim 10). Juni discloses the anesthetic imbibed in the bibulous pad in one preferred embodiment contains 10% benzocaine (column 3, lines 25-34), which addresses all the limitations of instant claims 8-10. Juni also discloses that an anesthetic such as **benzocaine** that is incorporated in a medical patch can be used to alleviate pain and skin irritations (column 3, lines 25-34 and column 1, lines 18-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claim 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juni (US Patent No. 6120792) as applied to claims 8-10 and 14 above, and further in view of Bernstein (US Patent No. 4997853) and Yamasaki et al. (US Patent No. 7018647).

Applicant Claims

The claimed subject matter of instant claims 8-10 are set forth above. Instant claim 11 recites the analgesic and anti-inflammatory patch according to claim 10, containing the ingredient having a counter-irritation effect in an amount of 0.01 to 30 wt % when it is one of 1-menthol, d1-menthol, d1-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil and eucalyptus oil, or in an amount of 0.001 to 5 wt % when it is one of capsaicin, one of capsicum extract and nonylic vanillylamide. Instant claim 12 recites the analgesic and anti-inflammatory patch according to any of claims 8 to 11, provided in the form of an aqueous poultice containing 10 to 80 wt % water. Instant claim 13 recites an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt % water, 0.5 to 20 wt % of benzocaine, and at least one ingredient having a counter-irritation effect selected from the listed recited in the instant claim.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Juni are disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

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Juni does not explicitly teach the concentration ranges for the ingredient having a counter-irritation effect and also does not explicitly teach the amount of water. These deficiencies are cured by the teachings of Bernstein and Yamasaki et al.

Bernstein teaches a method for treating superficial pain syndromes, said method comprising the step of topically applying to a patient having superficial pain, an effective amount of a composition comprising a therapeutically acceptable carrier and capsaicin, said **capsaicin being present in a concentration, by weight, from about 0.01% to about 1.0%**, said composition also including a topical anesthetic in a therapeutically effective amount, said anesthetic being present primarily to inhibit the local topical irritant effect of said capsaicin and whereby said capsaicin provides the primary relief for the pain syndrome (see claim 1). The anesthetic can be benzocaine (see claim 3).

Yamasaki et al. teach an external skin patch comprising a formulation of benzocaine (7% w/w) and other ingredients and 48.3 % of water (column 6, example 2, lines 28-54).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to incorporate in the medical adhesive patch a composition containing an ingredient with a counter-irritation effect such as capsaicin in a concentration of 0.001 to 5 wt %, because Bernstein teaches the same composition containing capsaicin in concentration of from about 0.01% to about 1.0% for the same intended purpose. Furthermore, the incorporation of an aqueous formulation is also taught by Yamasaki et al.. An ordinary skilled artisan would have been motivated to incorporate the capsaicin in concentration of from about 0.01% to about 5.0% because at higher concentrations the capsaicin can cause burning and irritation. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both references teach the similar compositions for the same intended purpose.

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Conclusion

Claims 8-14 are rejected. Claims 1-7 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

02/19/09

/PORFIRIO NAZARIO GONZALEZ/
Primary Examiner, Art Unit 1621